How Taiwan Pharmaceutical Industries Affected by and Cope with the U.S. Patent Linkage System

Pharmaceutical Industry Technology and Development Center

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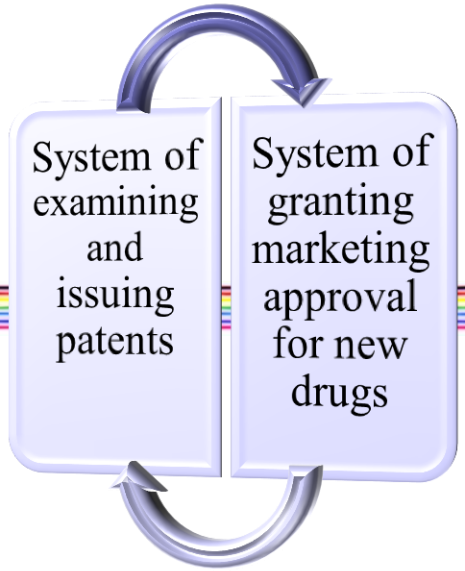
Outline

- Background
  - ✓ Hatch-Waxman Act
  - ✓ Current Status of Pharmaceutical Industry
- Stress on the U.S. Legislation
- Emergent Issues of Patent Linkage
- Corresponding Strategies
- Conclusion

Background‧Hatch-Waxman Act

- In 1984，Drug Price Competition and Patent Term Restoration Act
  - ✓ Patent Term Restoration
  - ✓ Bolar Provision
  - ✓ Data Exclusivity
  - ✓ Patent Linkage (PL)
  - ✓ ANDA
- Orange Book

U.S. Patent Linkage



- Organizations in Charge
  - ✓ **Patents are examined and issued by**：Patent and Trademark Office (PTO)
  - ✓ **Approvals for marketing new drugs are granted by**：Food and Drug Administration (FDA)
- ANDA Patent Certification
  - ✓ Paragraph I ~ IV

ANDA Patent Certification

Paragraph I	Paragraph II	Paragraph III	Paragraph IV
Required patent information has not been filed	Patent has expired	Patent not expired but will expire on a particular date	Patent invalid or non-infringed by generic applicant
FDA may approve ANDA immediately; one or more generic applicants may enter	FDA may approve ANDA immediately; one or more generic applicants may enter	FDA may approve ANDA effective on the date that the patent; one or more generic applicants may enter at that time	Generic applicant provides notice to patent holder and NDA filter; entry of the first filer may or may not occur

FD&C Act No. 355

Past Problem and Follow-up of U.S. Patent Linkage

- H-W amended in 2003：Medicare Prescription Drug, Improvement, and Modernization
- Final Rule on generic drugs published by FDA in 2003

✓ Only active ingredient, formulation, composition and indication-related patent information are disclosed in Orange Book

✓ Branded manufactures are limited to a single 30-month stay

In 2013, the Supreme Court in ***FTC v. Actavis*** case stated "anticompetitive effect"：
Federal Trade Commission (FTC) was ruled to involve more

Background‧Current Status of Pharmaceutical Industry

The U.S. becomes the third-largest importer of pharmaceutical product to Taiwan

Note：Ten medical-advanced countries (U.S., Canada, U.K., France, Belgium, Switzerland, Sweden, Germany, Japan, Australia)
Source：Trade Statistics of Customs Administration；Industrial Information of Development Center for Biotechnology

Stress on the U.S. Legislation

- Patent Term Restoration / Extension
  - ✓ Article 53 of Patent Act
- Bolar Provision
  - ✓ Paragraph 5, Article 40-2 of Pharmaceutical Affairs Act
- Data Exclusivity
  - ✓ Paragraph 2, Article 40-2 of Pharmaceutical Affairs Act
- Patent Linkage
  - ✓ System not established

Patent Term Restoration・Paragraph 1, Article 53 of Patent Act

Where a regulatory approval shall be obtained in accordance with other laws and regulations for the exploitation of an invention patent involving a pharmaceutical or agrichemical, or the manufacturing process thereof, if such regulatory approval is obtained after the publication of the concerned invention patent, the patentee may apply for one and only one extension of the patent term of said invention patent based on the first regulatory approval. The said regulatory approval is allowed to **be used only once for seeking patent term extension.**

The extension of the patent term approved under the preceding paragraph shall not exceed the length of time when the patent cannot be exploited because of the filing of a request for the regulatory approval with the central competent authorities in charge of the business. If the time needed to obtain the said regulatory approval exceeds five (5) years, the granted patent term extension shall still be five (5) years.

Bolar Provision
Data Exclusivity

- Paragraph 5, Article 40-2 of Pharmaceutical Affairs Act
  - ✓ The patent right of the new drug shall not be applicable to researches, teachings, or testing prior to the application for registration by the pharmaceutical firms.
- Paragraph 2, Article 40-2 of Pharmaceutical Affairs Act
  - ✓ Within five years after the issuance of a license for new drug of new molecular entity, any other pharmaceutical firm may not apply for evaluation and registration of the same items by citing the data submitted by the licensee without such licensee's authorization.

Emergent Issues of Patent Linkage

- Listings of Orange Book
- Effects of Patent Extension
  - ✓ Patent Extension Abused by Patentee
- Exporting / Manufacturing of Domestic Pharmaceutical Products
- Incentive of Domestic Manufacturers to Challenge Paragraph IV

Listing of Pharmaceutical Patent Database (U.S./Canada/Korea)

Drug Information	U.S. Orange Book	Canada Patent Register	Korea Green List
Product name	O	O	O
Application No. (Drug Identification Number)	O	O	O
Approval Date	O	O	O
Active Ingredient	O	O	O
Dosage Form; Route	O	O	O
Strength	O	O	O
Applicant	O	O	O
Applicant address	X	O	O
Patent Expiration date	O	O	O
Patent No.	O	O	O
Submission Type	X	O	X
Manufacturer	X	O	X
Manufacturer address	X	O	X
RX/OTC/DISCN:	O	X	X
TE Code	O	X	X

Note：Refer to Dr. Xiong, Zheng-hui's speech for "The 63rd Pharmaceutical Affairs Forum" held on November 18, 2014

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Drug Information	U.S. Orange Book	Canada Patent Register	Korea Green List
RLD	O	X	X
Submission number	X	O	X
Patent Filling date	X	O	O
Patent Granted date	X	O	O
Patent holder	X	X	O
Patent holder address	X	X	O
Agency	X	X	O
Agency address	X	X	O
Drug substance claim	O	X	X
Drug product claim	O	X	X
Detail information of claim	X	X	O
Use of Medicinal Ingredient	X	O	X
Patent Use Code	O	X	X
Patent Code	X	O	X
Delist Requested	O	X	X

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Corresponding Strategies I.

- Build a reasonable system in Taiwan together with complementary measures referring to international patent linkage systems and the included drug information
  - ✓ The incentive for domestic generic manufacturers to challenge branded drugs,
  - ✓ Auto-substitution of generic drugs to branded drugs,
  - ✓ A mechanism to suspend issuing marketing approval during patent litigation,
  - ✓ Corresponding measures to avoid patent extension being abused by patentee

Listing of Pharmaceutical Patent Database (U.S./Canada/Korea)

Country	U.S.	Canada	Korea
Registered Patent Details	N/A	N/A	Relevant claims and descriptions in connection with drugs are required to be registered as well.
Notice to Patentee	O	O	O
Notice Given by	Generic manufacturer	Generic manufacturer	Generic manufacturer
Failure of Notice	N/A	N/A	MFDS can then demand the generic manufacturer to give a notice. However, a notice will be given by MFDS directly if the generic manufacturer fails to give such notice. (Being amended)
Automatic "Stay"	O	O	Request needs to be made. MFDS will make the decision after reviewing. (Being amended)
"Stay " up to	30 months	24 months	N/A
Exclusivity	180 days	N/A	**12 months** from the date generic sales begin （Being amended）

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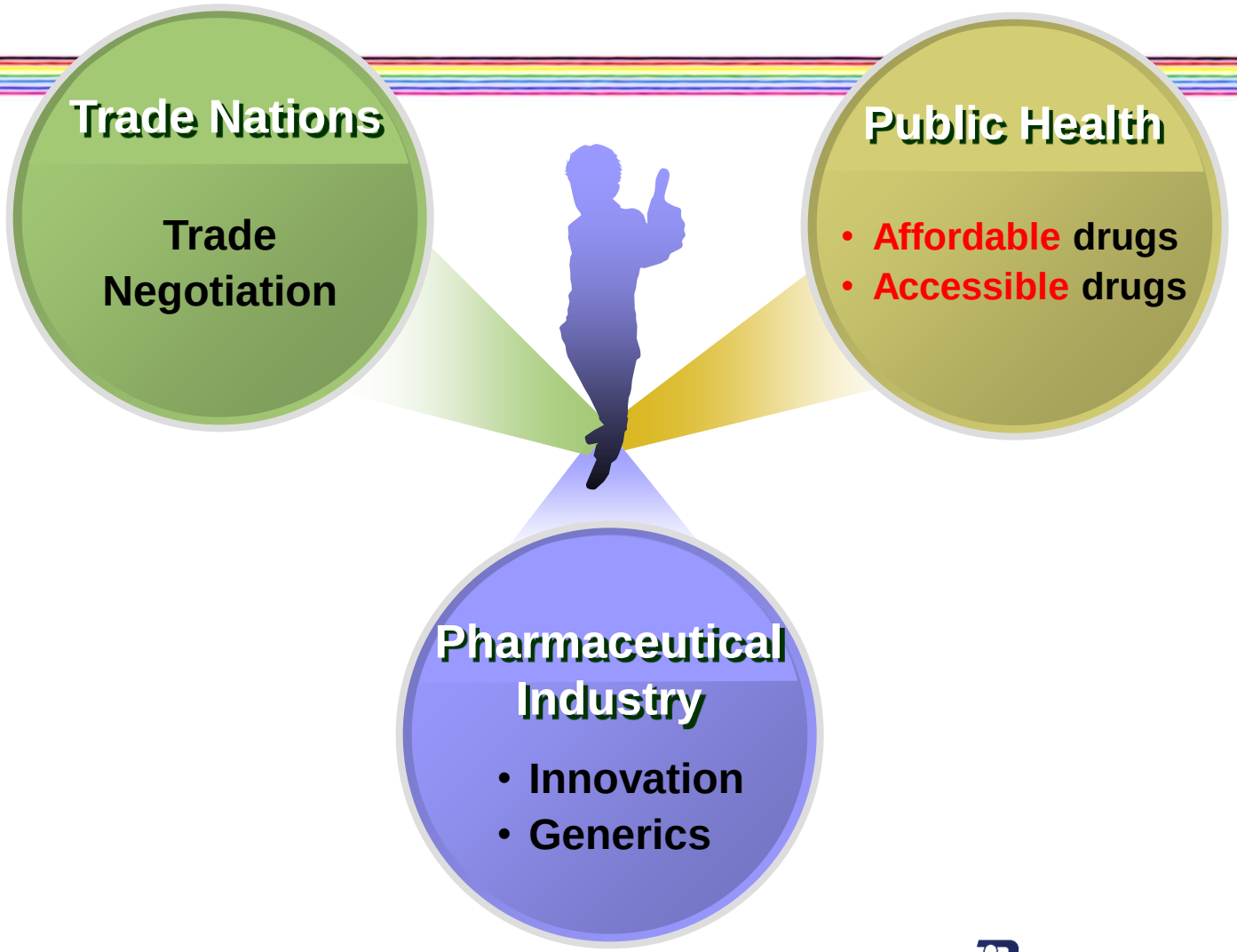
Corresponding Strategies II.

- Cultivation and training for domestic professionals
- Experts in related industries, the government, academia, and research institutes to be united
  - ✓ To build a more solid IPR environment through opinions and discussions
  - ✓ To pay respect to IPR and take account of industry development

Conclusion


Trade Nations
Trade Negotiation
Public Health
• Affordable drugs
• Accessible drugs
Pharmaceutical Industry
• Innovation
• Generics

Thank you